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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,557	08/25/2000	Christian Devaux	1017753-000152	5736
21839 7590 07/02/2008 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEYANDRIA, MA 22313, 1404			EXAMINER	
			PARKIN, JEFFREY S	
ALEXANDRIA, VA 22313-1404			ART UNIT	PAPER NUMBER
			1648	
			NOTIFICATION DATE	DELIVERY MODE
			07/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)	
	09/648,557	DEVAUX ET AL.	
Office Action Summary	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet with the c	orrespondence address	
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D. - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period. - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).	
Status			
Responsive to communication(s) filed on 19 L This action is FINAL . 2b) ☑ This 3) ☐ Since this application is in condition for allowed closed in accordance with the practice under	s action is non-final. ance except for formal matters, pro		
Disposition of Claims			
4) Claim(s) 31-53 is/are pending in the application 4a) Of the above claim(s) is/are withdrage 5) Claim(s) is/are allowed. 6) Claim(s) 31-53 is/are rejected. 7) Claim(s) 43 and 44 is/are objected to. 8) Claim(s) are subject to restriction and/or Application Papers	awn from consideration.		
9)☑ The specification is objected to by the Examin 10)☐ The drawing(s) filed on is/are: a)☐ acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11)☐ The oath or declaration is objected to by the E	cepted or b) objected to by the lead rawing(s) be held in abeyance. See ction is required if the drawing(s) is object.	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).	
Priority under 35 U.S.C. § 119			
 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureat * See the attached detailed Office action for a list 	nts have been received. Its have been received in Applicationity documents have been received au (PCT Rule 17.2(a)).	on No ed in this National Stage	
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal F 6) Other:	ate	

Serial No.: 09/648,557 Docket No.: COMA-037/00US

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Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the amendment submitted 19 December, 2007. Claims 31-53 are pending in the instant application.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. \S 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

The previous rejection of claims 1-10, 18, and 31-35 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is hereby withdrawn in response to applicants' amendment and arguments.

37 C.F.R. § 1.821-1.825

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For

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Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The sequence rules embrace all unbranched nucleotide sequences with ten or more bases and all unbranched, non-D amino acid sequences with four or more amino acids, provided that there are at least 4 "specifically defined" nucleotides or amino acids. The rules apply to all sequences in a given application, whether claimed or not. 37 C.F.R. § 1.821(d) stipulates that where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO.:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent Claim 31 references a decapeptide (KETWETWWTE) application. without a corresponding sequence identifier. However, the sequence appears to correspond to SEQ ID No.: 1 in the sequence listing. Applicants' attention is further directed to the final rules which were published in the Federal Register at 55 F.R. 18230 (May 1, 1990) and in the Official Gazette at 1114 O.G. 29 (May 15, 1990). The sequence rules went into effect on October 1, 1990. The sequence rules were subsequently revised effective July 1, 1998. See 63 F.R. 29634 (June 1, 1998) and 1121 O.G. 82 (June 23, 1998). The sequence rules were further revised on September 8, 2000 to allow submissions of the nucleotide and/or amino acid sequences and associated information on compact See 65 F.R. 54604 (Sept. 8, 2000) and 1238 O.G. 145 (Sept. 19, 2000). See also M.P.E.P. § 608.05 and § 2422.03. The specification is objected to because it fails to comply with the sequence requirements.

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37 C.F.R. § 1.75(c), Improper Dependent Claim

Claims 43 and 44 are objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 31 excludes a decapeptide consisting of the amino acid sequence KETWETWWTE (which corresponds to SEQ ID NO.: 1), yet claims 43 and 44 specify that the peptide of interest consists of SEQ ID NO.: 1. Further correction is required.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31-53 are rejected under 35 U.S.C. \$ 103(a) as being unpatentable over Morris et al. (1999) in view of Korber et al. (1998). Morris et al. (1999) provide an RT decapeptide

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 $^{^1}$ Applicants are advised that the Morris et al. (1999) reference was issued 27 August, 1999. The effective filing date of the instant application is 25 August, 2000. Since many journal articles are mailed and received prior to their issue date, the examiner is assuming the article was published more

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inhibitor corresponding to aa 395-404 of the HIV- $1_{\rm BH10}$ isolate. This peptide is highly efficient in abolishing the production of viral particles both in vitro and in infected cells. The peptide inhibits dimerization of the two subunits of HIV-1 RT. This is the exact same region utilized by applicants. p7 was a potent inhibitor and the HIV-1 RT displayed an association rate of only $0.31 \times 10^3 \text{ M}^{-1} \text{ s}^{-1}$ and an activation rate of only 0.018 h^{-1} in the presence of peptide as compared to an association rate of 5.1x104 M^{-1} s⁻¹ and an activation rate of 0.178 h⁻¹ in the absence of peptide (see Table 1, p. 24942; see Peptides Derived from the Connection Domain Inhibit RT Dimerization in Vitro, bridging paragraph, p. 24943). This teaching also discloses the utilization of MPG as a peptidyl carrier system to increase peptide delivery to the cell (see Cell Delivery of the Peptide Inhibitor, rt. col., p. 24943). The authors conclude that this peptide, as well as p7-MPG complexes, should prove quite useful as antiviral agents (see Conclusion, p. 24946). This teaching does not disclose peptide inhibitors other than p7 obtained from isolate $HIV-1_{BH10}$. However, Korber and colleagues provide multiple HIV-1, -2, and SIV RT sequence listings. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to make p7 inhibitory peptides and p7-MPG peptides that correspond to different viral isolates. This would make the peptides more useful as antivirals.

than one year before the effective filing date which renders it applicable under 35 U.S.C. \S 102(b). A request has already been submitted to the STIC to ascertain the true filing date of this publication. However, since this publication was available more than one year before applicants' earliest effective filing date, the declarations submitted under 37 C.F.R. \S 1.132 are not sufficient to overcome the rejection.

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Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin, Ph.D./ Primary Examiner, Art Unit 1648

18 June, 2008